510(k) Summary

MAY 0 8 2014

16 Ch Multipurpose Coil Variety

Date of Summary Preparation: March 25, 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

1. General Information

Importer/Distributor
Name and Address
NORAS MRI products GmbH
Leibnizstr.4
97204 Hoechberg / Germany

ERN: 3004929307
Owner/Operator Number: 9071737

Manufacturing Site
Name and Address
NORAS MRI products GmbH
Leibnizstr.4
97204 Hoechberg / Germany

ERN: 3004929307
Owner/Operator Number: 9071737

2. Contact Person

Zahed Sedighiani
MSc. Medical Engineering
Quality Assurance & International Licensing
NORAS MRI products GmbH
Leibnizstr.4
97204 Hoechberg
Germany
Tel: (+49) 931 / 29927-17
Fax: (+49) 931 / 29927-20
zahed.sedighiani@noras.de

3. Device Name and Classification

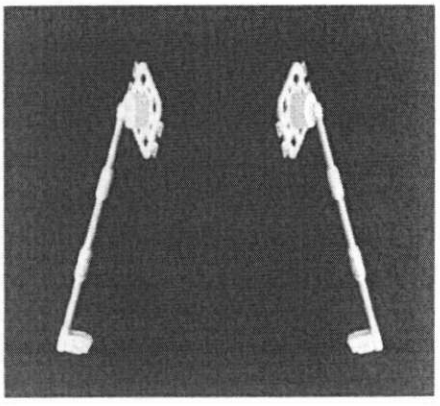
Trade Name:	**16 Ch Multipurpose Coil Variety**
Common Name:	**16 Ch Multipurpose Coil Variety**
Classification Name:	Magnetic Resonance Diagnostic Device
Classification Panel:	Radiology
CFR Number:	21 CFR § 892.1000
Device Class:	II
Product Code:	90MOS

4. Device Description

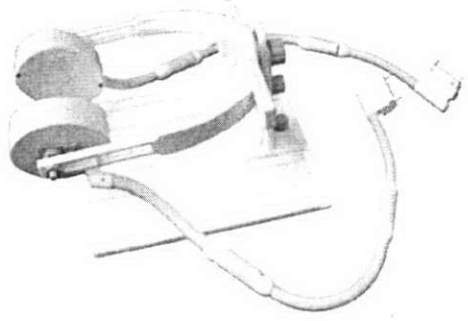
The **16 Ch Multipurpose Coil Variety** described in this document has been de-signed, depending upon model type, for use with a SIEMENS MRI system with field strength of 1.5 T or 3 T. The coil system serves only as a receiving coil for the reception of high frequency signals from the hydrogen -(^{1}-H) nuclei. The hydrogen nuclei are induced into precession by the transmitting coil of the MRT device. The processing magnetization induces potential differences in the 16 Ch Multipurpose Coil Variety which are digitized and further processed in the MRT system

The **16 Ch Multipurpose Coil Variety 1.5T (117235) 3T (117234)** are suitable for use with the following MRI systems:

MAGNETOM Avanto 1.5T
MAGNETOM Espree 1.5T
MAGNETOM Aera 1.5T
MAGNETOM Symphony a TIM 1.5T
MAGNETOM Trio a TIM 3T
MAGNETOM Skyra 3T
MAGNETOM Verio 3T



16 Ch Multipurpose Coil Variety



8 Ch Multipurpose Coil CPC

5. Intended Use / Indication for Use

The intended use of the **16 Ch Multipurpose Coil Variety 1.5T and 3T** is, in conjunction with a Magnetic Resonance Scanner, body imaging for diagnostic with a MRI system.

It is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of special regions of the human body. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

The outcome of this is diagnostic images of toes, feet, ankle, knee, finger, hand, wrist, elbow, shoulder, carotid artery, inner ear and other parts of the body with similar structure can be taken.

6. Substantial Equivalence

NORAS MRI products GmbH believes that, within the meaning of the Safe Medical Devices Act of 1990, the **16 Ch Multipurpose Coil Variety** is substantially equivalent to the following multipurpose coils:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Product Code	Comparable Properties
8 Ch Multipurpose Coil (CPC)	K083578	Jan 16 2009	90MOS	Intended Use / Indication for Use Environment Proton imaging High resolution of the body extremities Coil Design (Principle) Coil Design (Localization) Field of View Method of Decoupling
8-Channel Medium General Purpose Flex Coil	K111673	Dec 23 2011	90MOS	

K140252
Page 5 of 5

7. Summary of Technological Characteristics of the Principal Device as Compared with the predicate Device

Summary of technological characteristics of the **16 Ch Multipurpose Coil Variety** are the same as for the predicate devices **8 Ch Multipurpose Coil (CPC)** or **8-Channel Medium General Purpose Flex Coil**

The comarable technological characteristics are as follows:

- Coil Design (Principle) — Phased Array
- Coil Design (Localization) — Loop channels with preamplifier arranged oppositely in pairs
- Method of Decoupling — Active and Passive
- Mode of Operation — Receive only
- Mode of tuning — Tuned once in the factory

8. General Safety and Effectiveness Concerns

The **16 Ch Multipurpose Coil Variety** will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the IEC standards for safety issues with the Magnetic Resonance Imaging Devices, IEC 60601-2-33:2002. This will assure that the performance of this device can be considered safe and effective when used with the currently available Siemens MAGNETOM 1.5T/3T

The power tests which have been done by MRI manufacturer for the whole system can be found in Appendix C.

9. Conclusion as to Substantial Equivalence

NORAS MRI products GmbH believes that, within the definition of the Safe Medical Devices Act of 1990, the **16 Ch Multipurpose Coil Variety** is substantially equivalent to the predicate devices listed above.

Zahed Sedighiani
Quality and Regulatory Affairs Manager

March 25, 2014

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NORAS MRI products GmbH
% Mr. Zahed Sedighiani
Quality and Regulatory Management
Leibnizstr. 4
Hoechberg 97204
GERMANY

May 8,2014

Re: K140252
Trade/Device Name: 16 Ch Multipurpose Coil Variety – 1.5T (117235) 3T (117234)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: March 12, 2014
Received: March 14, 2014

Dear Mr. Sedighiani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140252

Device Name
16 Ch Multipurpose Coil Variety 1.5T / 3T

Indications for Use *(Describe)*

Intended Use / Indication for Use:

The intended use of the 16 Ch Multipurpose Coil Variety 1.5T and 3T is, in conjunction with a Magnetic Resonance Scanner, body imaging for diagnostic with a MRI system.
It is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of special regions of the human body. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.
The outcome of this is diagnostic images of toes, feet, ankle, knee, finger, hand, wrist, elbow, shoulder, carotid artery, inner ear and other parts of the body with similar structure can be taken.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."